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Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,127,425 was filed on December 12, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, SOLTAMOX® (tamoxifen citrate for oral administration), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would not be eligible for extension of the patent term under 35 U.S.C. § 156 because tamoxifen citrate was previously approved as a human drug under 21 U.S.C. § 355 (section 505 of the Federal Food, Drug and Cosmetic Act). It is noted that according to the application for patent term extension, tamoxifen citrate was first approved pursuant to 21 U.S.C. § 355(b)(1), while permission to market SOLTAMOX® (tamoxifen citrate for oral administration) was granted under 21 U.S.C. § 355(b)(2). There is no suggestion in the legislative history that the phrase "first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred" as used in 35 U.S.C. § 156(a)(5)(A) is intended to treat different subparagraphs of 21 U.S.C. § 355(b) as different provisions of law. The Supreme Court in Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 667, 674 (1990), made a distinction between the term "law" as broadly construed and a "provision of law," and also identified § 355 as a "provision" of the Federal Food, Drug, and Cosmetic Act under which new drugs are subject to premarket approval. Furthermore, there is evidence in the legislative history that Congress intended patent term extensions to apply to new chemical entities only. See Fisons v. Quigg, 1988 WL 150851, *7, 8 U.S.P.Q.2d 1491, 1497 (D. D.C. 1988), cited with approval in Fisons v. Quigg, 876 F.2d 99, 102, 10 U.S.P.Q.2d 1869, 1871 (Fed. Cir. 1989).

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda at (571) 272-7754 (telephone) or (571) 273-7754 (facsimile).

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